FDA REGULATIONS: TOPLINE

Source: https://www.industrydocuments.ucsf.edu/docs/nzgn0000

FDA Regulations Impact on Trade if Implemented :

Rules Effective February 28, 1997

- ***Minimum Sales Age***- Retailers may not sell cigarettes or smokeless tobacco to anyone under 18 years of age
- ***Proof of Age*** - Retailers must verify by photo ID that any person purchasing cigarettes or smokeless tobacco is at least 18 years of age. Customers over 26 years of age do not need to be asked to verify age. Age does not need to be verified in facilities that are off-limits to persons under 18 years of age.

Rules Effective August 28, 1997

- ***Self-Service Display Ban*** - Retailers may not offer cigarettes and smokeless tobacco from self-service displays, except in facilities where persons under 18 years of age (including employees) are not permitted.
- ***Vending Machine Ban*** - Retailers may not sell cigarettes or smokeless tobacco from vending machines, except in facilities where persons under 18 years of age (including employees) are not permitted.
- ***No Breaking Packs*** - Retailers may sell cigarettes only in unopened packages containing at least 20 cigarettes or in cartons. Retailers may sell smokeless tobacco only as packaged by the manufacturer.
- ***Mail-Order Sales*** - Retailers may fill mail-order requests, but may not redeem coupons sent by mail.
- ***Exterior Signage*** - Retailers within 1000 feet of a playground or school may not display exterior or outdoor advertising for cigarettes or smokeless tobacco. Permitted advertising must be black text on white background.

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FDA Regulations Impact on Trade if Implemented :

Rules Effective August 28, 1997 (cont'd)

- ***Interior Advertising*** - All point-of-sale advertising in any form for cigarettes or smokeless tobacco is in a black text on a white background format, except in facilities where persons under 18 years of age (including employees) are not permitted. For "adult only" facilities, interior advertising may be in color and use imagery provided the advertising is attached to an interior wall or fixture and is not visible from the outside.

- ***Established Name/Intended Use Statement*** - Each advertisement for cigarettes or smokeless tobacco must carry the product's "established name" and "intended use" -- "Cigarettes -- a Nicotine-Delivery Device for Persons 18 or Older".

- ***No Branded Merchandise*** - The retailer or manufacturer may not sell or give away non-tobacco merchandise bearing a cigarette or smokeless tobacco brand name or logo.

- ***No Free Samples*** - Coupon redemption is permitted in face-to-face transactions, but retailers and manufacturers may not give cigarettes or smokeless tobacco away as free samples.

- ***Non-Complying Items*** - No piece of current advertising complies with the FDA regulation.

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CIGARETTE / TOBACCO STORE TOPLINE

Convenience Store Options

- Continue with business as usual ***but*** develop contingency plans that will maintain / build cigarette business in a restricted access environment.
- Begin immediately with store-in-a-store concepts that will answer restricted access legislation ***and*** strengthen your business against cigarette / tobacco store proliferation.
- Enter the free-standing cigarette / tobacco store class-of-trade in selected markets.

Monitor both FDA *and* Local legislative activity. Let your government officials know how proposed laws will impact your business.

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ADDITIONAL FDA INFORMATION

Source: https://www.industrydocuments.ucsf.edu/docs/nzgn0000

FDA Control of Tobacco

Overview

- August, 1995: President Clinton uses executive authority to direct FDA to prepare proposed rule making to regulate tobacco to reduce youth access to tobacco products.
- August, 1995: Kessler at the FDA issues proposed rules.
- August, 1995: RJR and four other cigarette manufacturers file a lawsuit to block the Clinton Administration's attempt to grant the FDA authority to regulate cigarettes.
- *During the public comment period, the FDA received over 540,000 individual documents, the largest response ever of any FDA proposal. A majority of the responses opposed the FDA proposal.*
- August 20, 1996: The Department of Health and Human Services announces that teen-drug use in the U.S. has soared 105% from 1992 to 1995.
- August 21, 1996: President Clinton announces he will sign the executive order which accepts the proposed FDA rules to regulate tobacco before the Office of Management and Budget finishes their review and recommendations.
- August 23, 1996: President Clinton announces acceptance of final FDA rules.

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FDA Control of Tobacco
Summary of Final Rules

- **Severe advertising restrictions: No advertising within 1,000 feet of schools or playgrounds. Black & white text only advertising for all outdoor including billboards, signs inside and outside of buses: Advertising in publications is limited to black and white text only, except adult only publications. POS advertising restricted to black and white text except in age-restricted venues.**
- **Bans sampling.**
- **Bans premiums. Prohibits the sale and giveaway of products like caps and gym bags that carry cigarette or smokeless brand names and logos.**
- **Totally bans sports and event sponsorships including teams and entries. Corporate names may be used.**
- **Gives the FDA extraordinary authority to place even more harsh requirements on manufacturers, distributors, and retailers in the future.**

Source: https://www.industrydocuments.ucsf.edu/docs/nzgn0000

RJR Response to FDA Rulemaking

Over two years ago the United States Congress spoke out clearly on the issue of underage smoking by putting in place requirements on the state to implement steps to make it illegal to sell tobacco products to minors. That is the law. The Department of Health and Human Services has directed the states to take action now. The states have and continue to respond, establishing a minimum age of 18 years to purchase cigarettes, restricting access to vending machines, and requiring identification to purchase tobacco products.

While it is appropriate for the federal government to provide direction on the issue of underage smoking, the states should be responsible to implementation. In addition, the tobacco companies should and will continue voluntary efforts aimed at eliminating youth access to cigarettes.

Today there are more than 225 federal government agencies and offices spending over $100 million to review, oversee or control the tobacco industry. It is questionable whether adding the federal Food and Drug Administration will make the federal government more effective or more efficient.

Source: https://www.industrydocuments.ucsf.edu/docs/nzgn0000

FDA Talking Points

- **RJR doesn't think kids should smoke... PERIOD! That's why we strongly support effective programs like WE CARD and the Department of Health and Human Services new regulations.**
- **President Clinton's decision is pure political diversion. The day before Clinton makes his announcement on FDA, his own administration released a report that teen-drug use is skyrocketing . . . up 105% under the Clinton watch!**
- **The FDA's new ruling clearly is a violation of First Amendment Rights. We could be on our way to prohibition, and now the FDA has the authority to make it happen.**
- **All the Clinton administration's talk about protecting children can be solved by a new federal regulation enacted this year by HHS. HHS's new regulation requires all 50 states to show dramatic improvement in reducing youth smoking or loose millions of dollars in federal funding for other programs.**
- ***The HHS approach was authorized by Congress. FDA was not. President Clinton gives unelected bureaucrats at the FDA extraordinary power to dictate how a legal product is manufactured and marketed . . . this is a dangerous precedent!***

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State Cigarette Excise Tax Rates

Cents Per Pack - As Of October, 1996 *(FEDERAL = 24.0¢)*

Alabama	16.5¢
Alaska	29.0¢
Arizona	58.0¢
Arkansas	31.5¢
California	37.0¢
Colorado	20.0¢
Connecticut	50.0¢
Delaware	24.0¢
District of Col.	65.0¢
Florida	33.9¢
Georgia	12.0¢
Hawaii	60.0¢
Idaho	28.0¢
Illinois	44.0¢
Indiana	15.5¢
Iowa	36.0¢
Kansas	24.0¢
Kentucky	03.0¢
Louisiana	20.0¢
Maine	37.0¢
Maryland	36.0¢
Mass.	76.0¢
Michigan	75.0¢
Minnesota	48.0¢
Mississippi	18.0¢
Missouri	17.0¢
Montana	18.0¢
Nebraska	34.0¢
Nevada	35.0¢
New Hamp.	25.0¢
New Jersey	40.0¢
New Mexico	21.0¢
New York	56.0¢
No. Carolina	05.0¢
North Dakota	44.0¢
Ohio	24.0¢
Oklahoma	23.0¢
Oregon	38.0¢
Pennsylvania	31.0¢
Rhode Island	61.0¢
So. Carolina	07.0¢
South Dakota	33.0¢
Tennessee	13.0¢
Texas	41.0¢
Utah	26.5¢
Vermont	44.0¢
Virginia	02.5¢
Washington	81.5¢
West Virginia	17.0¢
Wisconsin	44.0¢
Wyoming	12.0¢

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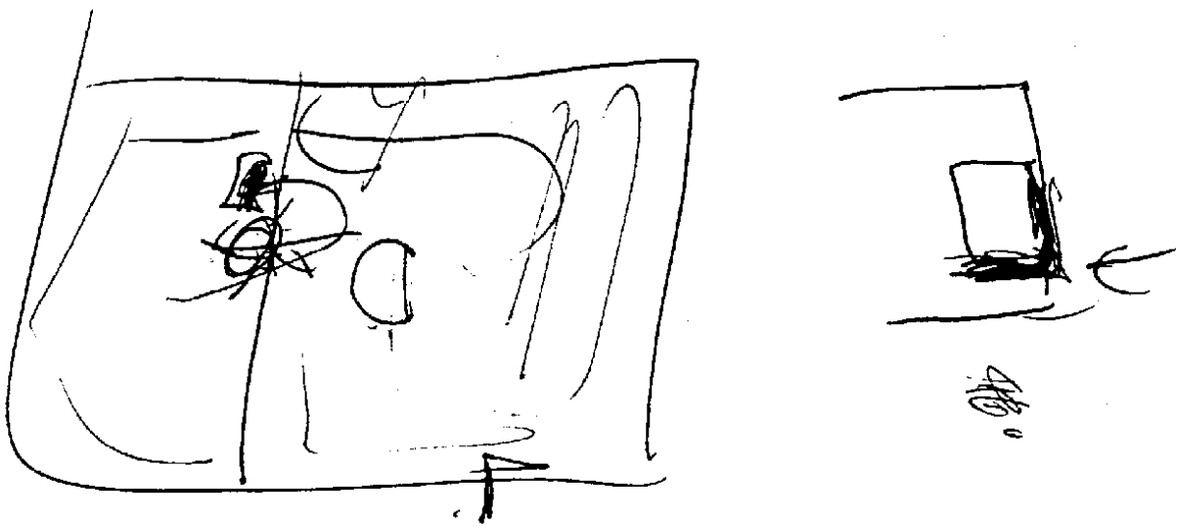

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